ATTACHMENT D

TO
BASIC ORDERING AGREEMENT
ATTACHMENT 1
STATEMENT OF WORK

LABORATORY QUALITY PROGRAM CHECKLIST

LABORATORY QUALITY PROGRAM CHECKLIST

Laboratory: _____ Audit Team Leader

_____ Assessment Date(s):

QA Manual No.: _____ Rev./Date_____ Phone Number_____

LABORATORY: **ASSESSOR:**

ITEM	REQUIREMENT	A	R	PARA/MANUAL	REMARKS
1.	***Criterion 1 Program*** Has a laboratory quality assurance plan (LQAP) or manual been written that follows the DOE 414.1 format and references: a) written policies, b) procedures or c) instructions?				
2.	Does the LQAP document define the laboratories policies and its commitment to: a) ethical standards, b) client confidentially and, c) implementation of safety and quality standards?				
3.	What is the name and title of designated individual responsible for developing, implementing, and routinely monitoring the LQAP program?				
4.	Does the LQAP describe the: a) organizational structure, b) functional responsibilities, c) levels of authority and d) interfaces for those managing, performing and assessing work?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
5	Have staff responsibilities and accountabilities been stated in writing such as: a) senior management responsible for establishing the scope of the LQAP and implementing, assessing, and continually improving an effective quality system, b) staff responsible for the quality of their work c) participating with the client developing analytical work scope, d) training and personnel development e) preparing, reviewing, approving, and issuing instructions, procedures, schedules and procurement documents, f) identifying and controlling hardware and software, g) calibrating and control of equipment used to measure/test, h) managing and operating facilities, i) conducting investigations and improving methods, j) acquiring, evaluating and reporting data and, performing maintenance, repair and improvements?				
6	Does the QA Representative report to the highest level of management within the laboratory?				
7	Does the QA program identify positions that can do the following: a) stop unsatisfactory work, b) initiate action to prevent reporting laboratory results from a measurement system that is out of control, c) prevent further reporting of measurements until corrective action has been completed, d) identify any method or procedure that poses a problem, and e) recommend, initiate or provide solutions through designated channels and monitor effectiveness of corrective actions.				
8	Has a system been established for reporting immediately to cognizant management and affected clients when there are regulatory actions toward the laboratory or its parent organization?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
1	***Criterion 2 Personnel Training and Qualification*** Determine how the laboratory management ensures that sufficient resources are maintained to perform the requirements of any statement of work requesting services. Is the management system for determining capability and capacity defendable?				
2	Does the laboratory have an internal analyst proficiency policy that provides a means to gauge and document the continuing competence of experienced individuals, as well as specifying additional training and documentation practices applicable to all personnel?				
3	Is there evidence that the subject policy has been followed and the measurement of staff's continuing competence documented?				
4	Are there documented records of indoctrination/training in: a) technical skills, b) laboratory analytical methods, c) QC procedures, d) Safety policies, e) Waste management practices and, f) Essential elements of the QA program before commencing work?				
5	Are the following records of indoctrination and training available for review: a) Attendance sheets, b) Training logs, c) Personnel training records, and d) a description of the training and indoctrination?				
6	Select 7 training records and review for compliance to internal requirements that represent this statement of work.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
7	Review personnel files and verify that the following criteria has been satisfied: a) laboratory personnel in management and supervisory roles with at least a BS or BA in chemistry or related science and 2 years experience; b) laboratory manager/director with at least a BS or BA in chemistry or related science and 5 years experience; c) written documentation to support qualifications of staff; d) an appendix listing personnel, their assignments, responsibilities, degrees of education and years of applicable experience (emphasis is this statement of work).				
1	***Criterion 3 Quality Improvement*** Has a system been established to: a) identify, b) document, c) correct, and d) prevent quality problems?				
2	Verify that there has been documented review by management to assess the effectiveness of the quality improvement system?				
3	Does the laboratory have a graded approach for determining what items, services and processes need to be addressed relative to the quality improvement system?				
4	Does correction include identifying the causes of problems and working to prevent recurrence?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
5	Has the laboratory addressed where corrective action is required as stated in the list below: a) documentation errors b) diverse trends in the analysis of standards, c) Failure to follow client analytical requests d) Failure to comply with approved technical and administrative procedures e) Failure to follow the preventive maintenance program f) Failures in the instrument systems or malfunctions in field equipment g) Failures in performance evaluation sample analysis audits, and assessments h) Validation and/or verification issues negatively impacting reported results i) Recurring adverse problems, including "near-miss" problems, such as "outside of warning limits," analysis blank problems, and other adverse trends j) Misidentification or mishandling of samples.				
6	Does the program make provision for: a) management responsibility for problem investigations, b) determining the significance of quality problems, c) taking effective corrective action based on the potential impact on the data quality, d) taking measures to eliminate or minimize recurrence of quality problems, e) determining if corrective actions have not been effective in preventing recurrence of quality problems, and analyzing quality-related information to identify trends that adversely impact quality and opportunities to improve items and processes?				
7	Has preventive action been defined and when preventive measures are implemented is their effect monitored to ensure that desired quality objectives are satisfied and maintained?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
8	Does the analysis of quality-related information include, where possible: a) identifying common work processes for item quality problems, b) conducting cause-and-effect analysis, and c) determining effective corrective and preventive actions from external sources? Does the QA program discuss where it is not possible and why?				
9	Verify that quality-related information to be analyzed includes, as a minimum, the following: a) Performance data, b) Audit reports, c) Surveillance reports, d) Nonconformance reports, e) Failure rates, f) Quality-related information from external sources, and g) Performance indicators.				
10	Determine if the method used for performing trend analysis identifies significant quality trends, and evaluates them for timely and appropriate corrective action. Are trends determined to be adverse to quality reported to the organization(s) responsible for corrective action?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
11	Verify that corrective action determinations include at least the following: a) Determining the events leading to the adverse condition, b) Determining the technical and work activities associated with the quality problem, c) Ascertaining the quality problem's generic implications, d) Determining the extent to which similar quality problems (or precursors to the problem) have been recognized, e) Determining the effectiveness of any corrective actions that were taken, f) Determining the impacts on the completed work, g) Recommending actions that can be taken by the responsible organization to preclude recurrence, and h) Determining if stopping the work associated with the activity is necessary.				
12	Are there documented and implemented procedures for the identification, documentation, evaluation, segregation (where practical), disposition, and notification to affected organizations of nonconforming items.				
13	Verify that out-of-control occurrences have been documented and staff assigned the responsibility for correction, documentation, and follow-up action.				
14	Has the QA program addressed out-of-control events and corrective action such as: a) Structural flaws in electronic data package deliverables, b) Corrective actions at the receiving level, c) Observations corrected at the bench, d) Corrective action taken by analyst, and e) Corrective actions taken by a supervisor.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
1	***Criterion 4 Documents and Records*** Does the company have a process for determining what activities affect quality and the methods used to document and control such activities?				
2	Are activities affecting quality prescribed by documented instructions, procedures or drawings that include quantitative or qualitative acceptance criteria that can be used to determine whether activities are satisfactorily accomplished?				
3	Verify that revisions to instructions, procedures, and drawings that affect the process or are technical in nature receive the same level of review and approval by the affected parties as the original document.				
4	Is there written document control that includes measures by which documentation can be controlled, tracked, and updated in a timely manner to ensure that applicability and correctness are established?				
5	Verify that the following document control measures have been documented and implemented: a) documents are reviewed for adequacy, b) approved for release by authorized personnel, and c) distributed to and used at the location of the prescribed activity.				
6	Obtain a current listing of analytical procedures and standard operating procedures, select a sample of ten, and verify that: a) each is controlled with a current revision status, b) being used at the location of the prescribed activity, c) out-dated documents have been removed from the work space, and d) there are data evaluation procedures for each analytical method and an entire data set are available, as appropriate.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
7 Records	Has the company established and implemented a system for: a) identifying, b) preparing, c) approving, d) transmitting, e) correcting, f) distributing, g) retaining, h) retrieving, and i) disposing of quality records. These systems shall ensure that records are maintained and controlled in a manner that facilitates retrospective review of all aspects of work performed to produce a reported result.				
8	Select four analytical reports and trace back through the record system to verify that records have been maintained and controlled in a manner that facilitates retrospective review of all aspects of work performed to produce a reported result.				
9	Does the Records procedure address that: a) quality records shall be legible, accurate, complete, and appropriate to the work accomplished, b) corrections will be made by drawing one line through the error, initialing and dating the error, and justifying the correction (if not self-explanatory), and c) changes to computerized data records shall be identified such that original and corrected entries are retrievable and the individual initiating the changes can be identified.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
10	Does the Records procedure make provision for: a) Specifications of items, data, and processes of which records are to be controlled, b) Requirements for the preparation, review, approval, and maintenance of records to accurately reflect completed work and to fulfill statutory requirements, c) Requirements and responsibilities for record transmittal, distribution, change, retention, protection preservation, traceability, archival, retrieval, and disposal, d) Verification that records received are legible and are in agreement with the transmittal document, e) Requirements for access to and control of the files, f) Procedures for the control, and client confidentiality accountability of records removed from the storage location, g) Procedures for filing of supplemental information and disposing of superseded records, h) Storage of records in a manner approved by the organizations responsible for the records, i) Replacement, restoration, or substitution of lost or damaged records, and j) Procedures for data correction, which include how corrections are to be made and establish who is authorized to change or correct data.				
11	Does the list of mandatory Records include: a) operating logs, b) results of reviews, c) inspections, d) tests, e) assessments, f) monitoring of work performance, g) material/sample analyses, h) calibration records and sub-contractor evaluations/results, i) qualifications of personnel, and j) procedures, and equipment.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
12	Verify that inspection and test records include, as a minimum: a) the identification of the inspector or data recorder, b) the type of observation, c) the results, d) the acceptability, and e) the action taken to correct any deficiencies noted.				
1	***Criterion 5 Work Process*** Has the company identified controlled conditions for the performance of work?				
2	Are analytical procedures listed by method number and matrix?				
3	Is there provision for documenting any method variances employed by the laboratory?				
4	Has the laboratory specified protocols for: a) reporting any incident that delays sample processing for a period of time, b) affects holding times, or c) delays work, and d) specifying the corrective action implemented.				
5	Have examples of forms used to document out-of-control events been provided in the LQAP.				
6	Has the company made provision for Environmental Protection Agency (EPA) method variance approvals? A listing of the typical method- Detection limits achieved for water, soil, and other matrices commonly analyzed by the laboratory shall be included. It is understood that these may vary with individual samples; however, procedures for determining limits of detection and the frequency of verification shall be outlined.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
7	Has the following issues been addressed: a) a listing of the typical method-detection limits achieved for water, soil, and other matrices commonly analyzed by the laboratory, b) procedures for determining limits of detection and the frequency of verification, and c) a summary of QC procedures and documentation to be employed in the day-to-day operation of the laboratory.				
8	Verify that the laboratory has made provision for the following as they relate to the different QC levels: a) Analysis of method and reagent blanks, b) Analysis of duplicates, spiked samples, spiked laboratory blanks, and reference or control standards such as EPA check standards; c) The criteria used to establish warning and control limits for the above types of QC samples; d) Documentation and examples of control data and control charts; e) The frequency of analyzing blanks and other QC samples; f) How data from QC samples are reported and reviewed; and g) Who reviews and makes decisions relative to QC data.				
9	Does the LQAP include: a) a listing of approvals from other agencies and states, and b) the laboratory's definition of accuracy, precision, completeness, and representativeness?				
10	Is there objective evidence of documentation and implementation for the following: a) Items are identified and controlled to ensure their proper use, b) Items are maintained to prevent their damage, loss or deterioration, c) Equipment used for process monitoring or data collection are calibrated and maintained, and Methods for evaluating measured parameters and data sets for accuracy, precision, completeness, and representativeness have been incorporated.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
11	Verify the documentation and implementation of: a) Mandatory use of reagent grade or higher purity chemicals when required by the specific analytical methods, b) Reagents checked prior to use and the supporting documentation of the checks filed in a manner that can be easily retrieved, c) Standards and reference materials traceable to a nationally recognized or consensus source, d) Preparation of standards, including any dilutions, be documented in a logbook, e) Standards assigned a unique identification number traceable to the original standard, f) Certificates of authenticity kept on file for all standards and reference materials, g) Laboratories develop and implement a SOP specifying the policy for the shelf life, labeling, and re-certification of reagents and stock solutions, h) Shelf life limits of standards, reagents, and reference materials labeled on the individual containers and status tracked, i) Standards and reference materials stored separately from samples and standards protected in a controlled cabinet or refrigerator, j) Organic standards properly refrigerated and stored as required by the specific analytical method, and k) Stock solutions or standards that are kept for long periods frequently checked for stability against quality control samples and documented in a logbook.				

LABORATORY: **ASSESSOR:**

ITEM	REQUIREMENT	A	R	PARA/MANUAL	REMARKS
1	***Criterion 7 Procurement*** Have Procurement processes been established and implemented such as the following: a) Contract documents require suppliers of all tiers to comply with technical and quality assurance requirements, including but not limited to, standards, measuring and test equipment, calibration services, and analytical test activities, b) Contracted items and services that have the potential to affect the quality of analytical tests are controlled to ensure conformance with contractual requirements by source evaluation and selection (pre-performance/pre-award survey), source verification, audit, or examination of items and services before use, c) Procurement documents reviewed for accuracy and completeness by qualified personnel prior to release, and d) Changes to procurement documents receive the same level of review and approval as the original documents, and e) Procurement documents specify the quality system elements for which the supplier is responsible and how the supplier's conformance to the customer's requirements will be verified.				
2	Do contract documents include provision for audit of supplier and subcontracted quality systems by the client?				
3	Are there documented and implemented procurement system controls that make provision for the following: a) Identifying applicable technical and administrative requirements from each Statement of Work for contracted services and items including acceptance criteria, b) The process for selecting and qualifying subcontractors, c) Establishing processes to ensure that qualified subcontractors continue to provide acceptable products and/or services, d) Accepting purchased items and/or services, e) Receiving and maintaining procurement records, including evidence of conformance, and f) Documenting nonconforming items and services.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
4	Is the following requirement documented: a) notify laboratory management when there are indications that subcontractors knowingly supplied items or services of substandard quality, and b) written justification by management on the decision to notify or not notify the DOE Office of the Inspector General?				
1	***Criterion 8 Inspection and Acceptance Testing*** Is there objective evidence of the following requirements being documented and implemented: a) services and processes are conducted using established acceptance and performance criteria, b) equipment used for inspection and tests are calibrated and maintained, c) current list of available (on hand) equipment types, models, and years and a general description of the facility, d) description of who performs major, preventative, and day-to-day equipment maintenance and how it is documented, e) documented schedule of preventive maintenance activities and a record of preventive maintenance performed, f) documented inventory of critical spare parts and/or equipment necessary to minimize the downtime of measurement systems related to analytical test samples that have a holding time of 48 hours or less, g) documented usage evaluation of the inventory at least annually, h) control processes maintained for all instrument spikes, replicates/splits, blanks, and other standards.				
2	Do laboratory data control processes include: a) performance of data quality checks prior to transmitting data on a frequency sufficient to provide full data interpretation, b) assuring error free data transmittal by using a proven computer program, or similar logic?				

LABORATORY: **ASSESSOR:**

ITEM	REQUIREMENT	A	R	PARA/MANUAL	REMARKS
3	Verify that the calibration program has addressed the following: a) calibration procedures listed by instrument type, b) balances, refrigerators, ovens, and other laboratory equipment maintained accurate and their performance monitored and documented, c) balances checked each day that they are used and calibrated at least annually by an independent company, d) refrigerator temperatures monitored daily, e) measuring and test equipment used for activities affecting the quality of analytical tests calibrated, adjusted, and maintained at prescribed intervals or prior to use against certified equipment or standards having known and valid relationships to nationally recognized standards, f) the bases for calibration is documented when no nationally recognized standards exist, g) calibration performed when the accuracy of equipment is suspect, h) measuring and test equipment is properly handled and stored to maintain accuracy, i) out-of-calibration equipment is tagged or segregated and not used until it has been re-calibrated, j) if any measuring or test equipment is consistently found to be out of calibration, it is repaired or replaced. k) calibration and control of standards required for any analytical test is specified in the analytical test procedure and in the calibration and control procedures if they are separate from the analytical procedure, l) tolerances for all measurements made during performance of an analytical test is specified, m) if a tolerance limit is not stated with a measurement value, then a system of tolerances is specified, n) when measuring and test equipment is found out of calibration, an evaluation is made and documented of the validity of any previous analytical test results --The results of such evaluation is promptly reported to the affected client, and o) records of calibration activities is maintained and calibrated equipment suitably marked to indicate calibration status.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
4	Does each calibration procedure specify the: a) standard to be used, b) required frequency of calibration, c) any special instructions necessary for obtaining reliable calibration data, and d) calibration control limits and the required treatment of data.				
1	***Criterion 9 Management Assessment*** Verify the documentation and implementation of a management assessment system that addresses: a) management with executive authority assessing the adequacy of the quality assurance program at least annually to ensure its continuing suitability and effectiveness in satisfying the requirements of this client requirements and the supplier's stated policies and objectives, b) reporting the results of management assessments, including the distribution of reports to affected organizations, and c) identifying and correcting problems that hinder the organization from achieving its objectives.				
1	***Criterion 10 Independent Assessment*** Have designated persons or organizations been assigned the responsibility for ensuring that an appropriate Quality Assurance program is established and for verifying that activities affecting the quality of the services specified in the Statement of Work have been correctly performed?				
2	Do the independent assessment organization have sufficient authority, access to work areas, and organizational freedom necessary to independently assess all activities affecting quality and to report the results of such assessments.				
3	Verify that personnel responsible for conducting independent assessments are technically qualified and knowledgeable in the areas assessed by reviewing assessment records, personnel records and through personal interviews.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
4	Is there objective evidence that assessment results have been documented, reported to and reviewed by the level of management with authority to affect any necessary corrective actions?				
5	Are there records that assessments have been conducted of subcontractors who perform work affecting the integrity of analytical results in order to assure continued conformance to contractual requirements?				
1	***Software Requirements*** Has the laboratory established systems design interface and Software Development Life Cycle (SDLC) documentation for each computer program that is: a) capable of being tested and evaluated independently and b) part of a software system affecting the quality of analytical tests?				
2	Verify that software design has the following: a) top-down structured development with major modules satisfying an identifiable contract requirement, b) approved by management and quality assurance personnel prior to use, c) data flow and program control being identifiable and traceable, d) program modules traceable to the applicable software design requirement, e) verification of computer programs affecting the quality of analytical tests are performed and documented, f) test requirements and acceptance criteria estimated prior to testing, g) software verification testing performed by qualified individuals not part of the development effort or who report to the Contractor's Manager responsible for software development, and h) models, methods, assumptions, and the computer environment used in the test are identified and documented,				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
3	Is there a written policy and procedures established to ensure the security of the software affecting the quality of analytical test results that includes: a) loss and unauthorized use of the computer software, b) both software and electronic data backed up at a documented frequency, and c) frequency of backup based on the amount of data and the impact of the loss of data or software on the organization.				
4	Has there been policy and procedures established and implemented to: a) evaluate, control, and correct data entry errors or program problems that affect the quality of analytical test results, b) report software errors found during use to the appropriate level of management, c) assign personnel to verify all errors and document the error notification and corrective actions in the case of field/laboratory-developed software, and d) include all users in error handling so that previously reported data may be evaluated and corrective actions tracked.				
1	***Sample Preparations*** Verify that the sample preparation process has documented and implemented the following: a) sample glassware and containers are either designated as disposable or cleaned according to recommended procedures that are listed in the individual Analytical Master Specifications, b) the laboratory-specific Standard Operating Procedure (SOP) for glassware is posted in the glassware cleaning area, and c) sample preparation areas are kept clean to avoid contamination or cross-contamination.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
2	Does the management program adequately document and implement the following: a) monitoring for contamination by use of a refrigerator storage blank during storage of all volatile organic samples, b) assessing the adequacy of these storage blank data and taking action for nonconforming conditions, c) analyzing refrigerator storage every 14 days when samples are being stored in the laboratory, d) making such data from the analysis available for review, and e) when required by the Statement of Work, a refrigerator storage blank will be used for the storage of mercury and tritium samples with elevated levels of contaminants.				
3	Verify that the following controls have been documented and implemented: a) routinely (as a minimum quarterly) monitor water used to prepare reagents, standards, samples, and solutions for purity and maintain the documentation of the checks, b) monitor daily the conductivity of the water from the purification system and record the results, c) ensure that water used for organic analysis meets the requirements for organic-free water as required by the specific methodologies, d) develop and implement a SOP for reagent and de-ionized water production for each laboratory, e) include the preventive and routine maintenance of the water purification unit in the SOP and associated documents, and f) include in the SOP the specific control criteria for reagent and de-ionized water and the corrective actions to be taken in the event of an out-of-control event.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
1	***Quality Control*** Does each laboratory ensure the following requirements are documented and implemented: a) for each analytical method a means is established to measure contamination levels, method accuracy, method precision, interferences, and loss of an analyte during preparation, b) these objectives are accomplished through instrument calibration with traceable standards and the evaluation of quality control sample analyses, c) each preparation batch, as applicable, contains a method blank and a Laboratory Control Sample (LCS) (QC check sample), d) organic preparation batches include a matrix and a matrix spike duplicate, e) radiochemistry and inorganic preparation batches contain a duplicate and a matrix spike, f) ICP analysis includes an inter-element check standard and the LCS is prepared from an independent source with spikes carried through the entire analytical process, g) primary standards have traceable documented certificates of accuracy and/or purity, h) procedures are developed for the review and acceptance of QC sample results, including established limits for data, and i) maintain statistical control methods for accuracy and precision.				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
2	Verify that the following criteria has been addressed: a) acceptability of QC samples to performance criteria are checked as soon as possible after data generation, and these checks documented, b) corrective actions are established for QC sample results that exceed the control limits, c) QC samples are used when practical to evaluate contamination, precision, and accuracy of an analytical system, d) method blanks, or reagent blanks, are through the complete sample preparation and analytical procedure, e) duplicates are intra-laboratory split samples and used to document the precision of a method, and f) reference materials, matrix spike samples, tracers, surrogates, interference checks, and calibration checks are employed to measure some component of accuracy. .				
1	***Statistical Control Methods*** Is there objective evidence that each laboratory has developed and implemented statistical control methods?				
2	Are statistical control methods developed and used in a real-time manner?				
3	Are statistical control methods accessible to the individual performing the analyses, data reviewers, and to the quality assurance staff?				
4	Has the laboratory provided a brief description of the basic methodology for control methods?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
1	***Good Automated Laboratory Practices (GALP)*** Are the Principles of the Good Automated Laboratory Practices (GALP) used by the laboratories to ensure the reliability of data by including: a) traceability, b) accountability, c) standardized procedures, d) adequate resources, and e) the availability of documentation for conformance to the requirements?				
2	When the LIMS or equivalent system is used to collect, analyze, process, or maintain raw data, does laboratory management ensure that: a) personnel clearly understand the function(s) they are to perform and have adequate education, training, and experience to perform assigned functions, b) personnel, resources, and facilities are adequate and available as scheduled, c) corrective actions are promptly taken in response to any deficiencies reported from assessments of the system, d) procedures have been written, reviewed, approved and implemented to the GALP criteria, development methods are based on the size and nature of software being developed and in accordance with the EPA Information Resources Management Policy Manual, Chapter 17?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
1	***Sample Control and Building Security*** Verify that physical or administrative controls exist to ensure that: a) Chain of Custody (COC) is not broken during times that laboratory staff are present or not present, b) Visitor access is controlled by positive administrative controls and strict escort rules developed for all visitors, and c) The facility has controlled entrance and egress points.				
1	Selected Management Requirements Has the laboratory established and implemented a Decontamination & Decommissioning (D&D) Financial Assurance Plan, including funding provisions?				
2	Can the laboratory provide evidence of financial assurance sufficient to disposition all sample residues and laboratory wastes and decommission the facility per requirements of the Nuclear Regulatory Commission (NRC) or Agreement States?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
3	Verify participation of the laboratory in one or more of the following Performance Evaluation (PE) Programs for a minimum of one year: a) Water Pollution (WP) Laboratory PE operated by the Environmental Protection Agency (EPA) National Exposure Research Laboratory in Cincinnati, Ohio (NERL-Ci). b) Water Supply (WS) Laboratory PE operated by the National Exposure Research Laboratory - Cincinnati, Ohio (NERL-Ci). c) PE Studies Programs for Radioactivity measurements, operated by the EPA Center for Risk - Las Vegas, formerly known as EMSL - Las Vegas (EMSL-LV). d) Environmental Measurements Laboratory (EML) QA Program operated by DOE Environmental Laboratory (EML) in New York, New York, for Radioactivity measurements. e) Quarterly Blind (QB) PE, operated by EPA Office of Emergency and Remedial Response through EPA Center for Risk. f) Mixed Analyte Performance Evaluation Program (MAPEP), operated by DOE Radiological and Environmental Science Laboratory (RESL) at Idaho National Engineering Laboratory (INEL) site.				
4	Does the laboratory participate in applicable rounds of external PE programs? Are results of PE programs utilized in the Integrated Performance Indicator Program (IPIP)?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
5	Verify laboratory participation in two single-blind, single-concentration performance testing (PT) studies provided by an approved supplier. Obtain objective evidence that the subject PT supplier has been approved by the Proficiency Testing Oversight Body (PTOB)/ Proficiency Test Provider Accreditor (PTPA) administered by the National Environmental Laboratory Accreditation Program (NELAP). Are the single-blind studies related to regulatory or environmental programs, matrix types, or analytes for the analytical disciplines that each laboratory performs (i.e., Inorganic, Organic, Radiochemistry)?				
6	Does the laboratory have state and federal licenses for the handling of Radiological material? Is the laboratory capable of receiving and analyzing: a) samples that contain manmade induced radioactivity to include isotopes of atomic number 3-92, b) a minimum of one gram of Source Materials (10CFR) and Special Nuclear Materials containing a minimum of one gram of U235 (10CFR), and c) having on-hand inventory of minimum of one mCi activity for isotopes 3-92 on the periodic table?				
7	Has the laboratory documented and implemented: a) a Radiological Control Plan, and b) Radiological Receipt acceptance protocols/procedures.				
8	Are laboratory personnel qualified/certified to ship and receive radiological material?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
9	Has a waste management plan been documented and implemented that covers the following: a) identifying all waste streams generated by the laboratory, b) identifying the process for managing and disposition of the various waste streams, c) tracking the disposition of the waste samples by Sample Data Group (SDG), d) Administrative Programs to demonstrate compliance for all effluent discharges as required by regulatory agencies, e) training procedures, training schedule, and management of training records in the following areas: waste management, waste shipping, waste handling, and radioactive materials control, f) Radioactive volumetric and surface release policies, g) applicable permits and licenses to handle hazardous and radioactive waste, h) Policy or direction on how to conduct waste brokering and Transport, Storage, and Disposal Facility (TSDF) evaluation to ensure proper dispositioning of waste, and i) Tracking of individual sample containers from receipt to final disposition.				
10	Verify that the laboratory has a radioactive materials inventory program capable of tracking standards, tracers, and all licensable samples. Select five (5) samples from a listing of such material and verify that the laboratory can demonstrate effectively tracking and monitoring, on a real-time basis, the radioactive materials within the possession of the laboratory against the specific quantities, isotopes, and types listed in the radioactive materials license. Can the laboratory demonstrate that this program ensures that the radioactive materials license will not be exceeded?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
11	How does the laboratory determine and then demonstrate compliance or exempt status with the environmental, safety and health requirements of applicable laws, regulations, and standards? Has the laboratory addressed the following regulatory requirements: a) Occupational Safety and Health Administration (OSHA), b) DOE, c) EPA, d) NRC, and e) Department of Transportation (DOT), and/or their State or Local counterparts. Obtain documented objective evidence for the audit file.				
12	Does the laboratory maintain bound laboratory notebooks that address the following: a) detail the sample bottle preparation and analytical work, b) including the analyses being performed, c) samples being analyzed, d) procedures used, e) reading taken, f) calculations performed, g) analytical results, and h) any observations during analysis? Do the notebooks follow EPA guidance and are they filed at the laboratory?				

LABORATORY:				ASSESSOR:	
ITEM	**REQUIREMENT**	**A**	**R**	**PARA/MANUAL**	**REMARKS**
13	Verify that the laboratory has documented and implemented standard operating procedures for the following areas: a) Sample tracking and COC (from receipt to disposition), b) Sample preparation (including subsampling), c) Sample storage and security, d) Proper sample disposition, e) Prevention of sample contamination, f) Facility security, g) Data reduction, verification, and reporting, h) Acceptance criteria (e.g., QC limits, calibrations, etc.), i) Document control, j) Data packages review prior to submittal, k) Shipment of deliverables, l) Records disposition, m) Preparation and traceability of standards, n) Catastrophic failure of a refrigerator, freezer unit, o) Glassware cleaning, p) Equipment maintenance, and q) Qualification of personnel and training.				